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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|----------------------|
| 10/572,563 | 05/09/2008 | Jiunn-Liang Ko | 8964-000031/US | 5069 |
| 30593 | 7590 | 10/21/2011 | EXAMINER | |
| HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 8910 RESTON, VA 20195 | | | | NAVARRO, ALBERT MARK |
| ART UNIT | | PAPER NUMBER | | |
| 1645 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 10/21/2011 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/572,563 | KO ET AL. | |
| | Examiner | Art Unit | |
| | Mark Navarro | 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 September 2011.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
- 4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) Claim(s) 1,2,5-8,11,12,17,19-21 and 24-30 is/are pending in the application.
 - 5a) Of the above claim(s) 1,2,5-8,11,12,17,19-21 and 24-28 is/are withdrawn from consideration.
- 6) Claim(s) _____ is/are allowed.
- 7) Claim(s) 29 and 30 is/are rejected.
- 8) Claim(s) _____ is/are objected to.
- 9) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 10) The specification is objected to by the Examiner.
- 11) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 14, 2011 has been entered.

Claims 3-4, 9-10, 13-16, 18, and 22-23 have been cancelled. Accordingly, claims 1-2, 5-8, 11-12, 17, 19-21, and 24-30 are pending in the instant application, of which claims 1-2, 5-8, 11-12, 17, 19-21, and 24-28 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

1. The rejection of claims 29-30 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Evans et al in light of Murasugi et al is withdrawn in view of Applicants amendment.

The following new ground of rejection is applied to the amended claim:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al and Murasugi et al in view of Egel-Mitani et al.

The claims are directed to a method of modulating immunological activities comprising transforming yeast cells with an amino acid sequence including SEQ ID NO: 1; expressing a recombinant protein; and orally administering the recombinant protein isolated from the yeast cells or the yeast cell expressing the recombinant protein.

Evans et al (US Patent Number 5,928,896) disclose of compositions of immunomodulatory peptides comprising Ling-Zhi-8 for oral administration. (See Immunomodulator peptides section).

Murasugi et al (Journal of Biological Chemistry Vol. 256, No. 4, pp 2486-2593, 1991) disclose of the nucleotide sequence encoding the amino acid sequence of Ling-Zhi-8 and its recombinant expression. (See page 2489).

Neither Evans et al nor Murasugi et al teach of SEQ ID NO: 1.

SEQ ID NO: 1 of the instant invention encodes with 100% identity the same Ling Zhi-8 protein taught by Evans et al and Murasugi et al, however it is codon optimized for yeast expression.

Egel-Mitani et al (Gene Vol. 73, pp 113-120, 1988) teach that it was routine in the art at the time of the invention to express heterologous genes in *Saccharomyces cerevisiae*, and that when doing so it was necessary to optimize codons frequently used by yeast. (See abstract and page 114). Egel-Mitani et al further teach that when codons were substituted to conform with yeast codon usage, heterologous expression levels increased. (See page 118).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have taken the known DNA sequence for Ling-Zhi-8 as taught by Murasugi et al and optimize it for expression in a yeast cell as taught by Egel-Mitani et al, thereby arriving at the nucleotide sequence comprising SEQ ID NO: 1. It would have been further obvious to administer the resulting expressed protein orally in view of Evans et al administering the identical protein orally.

Additionally, Applicants have attempted to distinguish over the teaching of Evans et al because Evans utilizes the additional polymer to protect the peptide and did not disclose or imply that the entire Ling-Zhi-8 can be orally administered directly without any forms of protection. However, Applicants are respectfully directed back to their own claim language, claim 29, which recites: "A method of modulating immunlogical activities **comprising**.... (Emphasis added). The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended.").< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). In other words, Applicants claim language of "comprising" allows within its breadth the additional coated polymer, and therefore cannot be used to distinguish over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571)272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
October 10, 2011